A1

determining the IL-1 [or TNF-A] genotype of the individual to identify whether the subject contains an low birth weight (LBW) associated allele and selecting a therapeutic that compensates for an LBW causative functional mutation that is in linkage disequilibrium with the polymorphism.

25. **(Amended)** The method of claim 17, wherein the therapeutic is selected from the group consisting of: a modulator of an IL-1 activity and [or] a modulator of a TNF activity.

A2

26. **(Amended)** The method of claim 25, wherein the modulator of an IL-1 activity [IL-1] is IL-1α.

27. **(Amended)** The method of claim 25, wherein the modulator of an IL-1 activity [IL-1] is IL-1β.

28. **(Amended)** The method of claim 25, wherein the modulator of an IL-1 activity [IL-1] is IL-1Ra.

33. **(Canceled)**

34. **(Canceled)**

35. **(Canceled)**

36. **(Canceled)**

37. **(Canceled)**

38. **(Canceled)**

39. **(Canceled)**

40. **(Canceled)**

41. **(Canceled)**

42. **(Amended)** A method for treating a subject predisposed to having a low birth weight baby (LBW) comprising the steps of: determining the IL-1 [or TNF-A] genotype of the individual to identify the presence of an LBW associated allele; and administering to the subject a therapeutic that compensates for an LBW causative mutation that is in linkage disequilibrium with the polymorphism.

A3

50. **(Amended)** The method of claim 42, wherein the therapeutic is selected from the group consisting of: a modulator of an IL-1 activity and [or] a modulator of a TNF activity.

A4

51. **(Amended)** The method of claim 50, wherein the modulator of an IL-1 activity [IL-1] is IL-1α.

52. **(Amended)** The method of claim 50, wherein the modulator of an IL-1 activity [IL-1] is IL-1β.

53. **(Amended)** The method of claim 50, wherein the modulator of an IL-1 activity [IL-1] is IL-1Ra.

58. **(Canceled)**

59. **(Canceled)**

60. **(Canceled)**

61. **(Canceled)**

62. **(Canceled)**

63. **(Canceled)**

64. **(Canceled)**

65. **(Canceled)**

66. **(Canceled)**

67. **(Canceled)**

68. **(Canceled)**

69. **(Canceled)**

70. **(Canceled)**

71. **(Canceled)**

72. **(Canceled)**

73. **(Canceled)**

74. **(Canceled)**

75. **(Canceled)**

76. **(Canceled)**

77. **(Canceled)**

78. **(Canceled)**

79. **(Canceled)**

REMARKS:

Claims 9-16, 33-41 and 58-79 are canceled without prejudice solely to comply with this restriction requirement. Applicants reserve the right to pursue the same or equivalent claims in later applications. Claims 17 and 42 are amended solely to comply with this restriction requirement, and Applicants reserve the right to pursue any subject matter removed by these amendments in later applications. Claims 25-28 and 50-53 are amended solely to put the claims in proper Markush group format. These amendments do not constitute a narrowing of scope. No new matter has been introduced.

In the restriction requirement under 35 U.S.C. § 121, the Examiner alleges that there are fourteen distinct groups of claims. Groups I and III are reproduced below:

> I. Claims 1-8 and 80-84, drawn to methods to detect a predisposition to adverse pregnancy outcome, classified in Class 435, subclass 6.
>
> III. Claims 17-32 and 42-57, drawn to methods of treatment and methods for selecting a therapeutic regimen by detecting an IL-1 genotype, classified in Class 514, subclasses 1 and 44.

Applicants respectfully traverse this restriction to one of fourteen groups. The Examiner's attention is directed to M.P.E.P. § 803, which states that: "If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." Thus, for a restriction requirement to be valid, the Examiner must establish the following two criteria: